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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V.; N.V. ORGANON; ORGANON USA LLC; and ORGANON LLC, Plaintiffs, v. XIROMED PHARMA ESPAÑA, S.L.; XIROMED, LLC; and INSUD PHARMA, S.L.U., Defendants.	Civil Action No. 25-2254 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Sharp & Dohme B.V. ("Merck B.V."), N.V. Organon ("N.V. Organon"), Organon USA LLC ("Organon USA"), and Organon LLC ("Organon LLC") (collectively, "Plaintiffs"), by their attorneys, bring this complaint against Defendants Xiromed Pharma España, S.L. ("Xiromed España"), Xiromed, LLC ("Xiromed, LLC"), and Insud Pharma, S.L.U. ("Insud") (collectively, "Xiromed" or "Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271(e)(2), the Drug Price Competition and Patent

Term Restoration Act of 1984, and 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), arising from Xiromed's submission of an Abbreviated New Drug Application ("ANDA"), No. 217698 ("Xiromed's ANDA"), with the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a purported generic version of NEXPLANON® (etonogestrel implant, 68 mg/implant) prior to the expiration of U.S. Patent Nos. 8,722,037 ("the '037 patent") and 9,757,552 ("the '552 patent") (together, "the patents-in-suit"). NEXPLANON® was first approved by FDA in 2011 and is a progestin indicated for use by women to prevent pregnancy.

PARTIES

2. Plaintiff Merck B.V. is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, 2031 BN Haarlem, Netherlands. Merck B.V. is a wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation, which has its principal place of business at 126 E. Lincoln Ave, Rahway, New Jersey 07065. Merck B.V. is the owner and assignee of the patents-in-suit.

3. Plaintiff N.V. Organon is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Kloosterstraat 6, 5349 AB Oss, Netherlands. N.V. Organon has rights to practice and enforce the patents-in-suit as an exclusive licensee in the United States.

4. Plaintiff Organon USA is a limited liability company organized and existing under the laws of the State of New Jersey with its principal place of business at 30 Hudson Street, Jersey City, New Jersey 07302. Organon USA is the holder of New Drug Application ("NDA") No. 021529 for NEXPLANON® (etonogestrel implant, 68 mg/implant).

5. Plaintiff Organon LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 30 Hudson Street, Jersey

City, New Jersey 07302. Organon LLC is responsible for marketing and selling the NEXPLANON® product in the United States.

6. On information and belief, Defendant Xiromed España is a limited liability company organized and existing under the laws of Spain, with a place of business at Calle de Manuel Pombo Angulo, 28, 3rd floor, Hortaleza, 28050, Madrid, Spain.

7. On information and belief, Defendant Xiromed, LLC is a limited liability company organized and existing under the laws of the State of New Jersey with its principal place of business at 180 Park Ave, Suite 101, Florham Park, New Jersey 07932.

8. On information and belief, Defendant Insud is a single-member limited liability company organized and existing under the laws of Spain, with a principal place of business at Calle de Manuel Pombo Angulo, 28, 3rd floor, Hortaleza, 28050, Madrid, Spain. On information and belief, Insud is the ultimate parent of both Xiromed España and Xiromed, LLC. On information and belief, Xiromed España and Xiromed, LLC are the business entities through which Insud markets and sells generic drug products in the U.S. market.

9. On information and belief, Defendants are in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

10. By a letter dated February 20, 2025 ("Xiromed Notice Letter"), Xiromed notified Plaintiffs that Xiromed had submitted to the FDA Xiromed's ANDA for approval to market and sell in the United States a purported generic version of NEXPLANON® (etonogestrel implant, 68 mg/implant) (referred to herein as the "Xiromed ANDA Product"), prior to the expiration of the patents-in-suit.

11. On information and belief, Defendants have acted and continue to act in concert with respect to the preparation, submission, and prosecution of Xiromed's ANDA, as well as the preparation and submission of the Xiromed Notice Letter.

12. On information and belief, Defendants know and intend that upon approval of Xiromed's ANDA, Defendants will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Xiromed ANDA Product throughout the United States, including in New Jersey. On information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to the Xiromed ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Defendants participated, assisted, and cooperated in carrying out the acts detailed in this Complaint.

13. On information and belief, following any FDA approval of Xiromed's ANDA, Defendants will act in concert to manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Xiromed ANDA Product throughout the United States, including in New Jersey.

JURISDICTION AND VENUE

14. Plaintiffs incorporate each of the preceding paragraphs 1-13 as if fully set forth herein.

15. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271, for infringement of the patents-in-suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 & 1338(a).

16. Xiromed España is subject to personal jurisdiction in New Jersey because, among other things, Xiromed España itself, including by and through its affiliate Xiromed, LLC,

purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Xiromed España itself, and through its affiliate Xiromed, LLC, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Xiromed España is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Xiromed, LLC, and therefore the activities of Xiromed, LLC in this jurisdiction are attributable to Xiromed España. Xiromed España also directed and sent the Xiromed Notice Letter to Organon USA at its headquarters in Jersey City, New Jersey.

17. Xiromed España, in concert with Xiromed, LLC, has committed an act of infringement in this judicial district by filing Xiromed's ANDA with the intent to make, use, sell, offer for sale, and/or import the Xiromed ANDA Product in or into this judicial district, prior to the expiration of the patents-in-suit.

18. Additionally, this Court has personal jurisdiction over Xiromed España because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Xiromed España is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Xiromed España has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Xiromed's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Xiromed España satisfies due process.

19. On information and belief, Xiromed España has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g.*, *American Regent, Inc. v. Xiromed, LLC et al.*, No. 2:24-cv-07811-BRM-CLW (D.N.J. July 16, 2024) (consolidated into *In re Selenious Acid Litigation*, No. 2:24-cv-07791).

20. This Court has personal jurisdiction over Xiromed, LLC because Xiromed, LLC is a limited liability company organized under the laws of the State of New Jersey and having a principal place of business in New Jersey.

21. Xiromed, LLC is also subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Xiromed, LLC is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID. No. 0600430486. On information and belief, Xiromed, LLC is registered with the New Jersey Department of Health as a drug manufacturer (Drug and Medical Device Certificate of Registration Number 5004977).

22. On information and belief, Xiromed, LLC develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

23. On information and belief, Xiromed, LLC has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g.*, *American Regent, Inc. v. Xiromed, LLC et al.*, No. 2:24-cv-

07811-BRM-CLW (D.N.J. July 16, 2024) (consolidated into *In re Selenious Acid Litigation*, No. 2:24-cv-07791).

24. Insud is subject to personal jurisdiction in New Jersey because, among other things, Insud itself, as well as by and through its subsidiaries and generic arms Xiromed España and Xiromed, LLC, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Insud itself, and through its subsidiaries and generic arms Xiromed España and Xiromed, LLC, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Insud is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Xiromed España and Xiromed, LLC, and therefore the activities of Xiromed España and Xiromed, LLC in this jurisdiction are attributable to Insud. Insud, through its subsidiaries and generic arms Xiromed España and Xiromed, LLC, also directed and sent the Xiromed Notice Letter to Organon USA at its headquarters in Jersey City, New Jersey.

25. Insud, in concert with Xiromed España and Xiromed, LLC, has committed an act of infringement in this judicial district by filing Xiromed's ANDA with the intent to make, use, sell, offer for sale, and/or import the Xiromed ANDA Product in or into this judicial district, prior to the expiration of the patents-in-suit.

26. Additionally, this Court has personal jurisdiction over Insud because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Insud is a foreign defendant not subject to general personal jurisdiction in

the courts of any state; and (c) Insud has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Xiromed's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Insud satisfies due process.

27. Defendants have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Xiromed ANDA Product, that will be purposefully directed at New Jersey and elsewhere in the United States.

28. On information and belief, Defendants have systematic and continuous contacts with New Jersey; have established distribution channels for drug products in New Jersey; regularly and continuously conduct business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through their subsidiaries, agents, or affiliates; have purposefully availed themselves of the privilege of doing business in New Jersey; and derive substantial revenue from the sale of drug products in New Jersey.

29. On information and belief, if Xiromed's ANDA is approved, Defendants will manufacture, market, promote, sell, offer for sale, import, use, and/or distribute the Xiromed ANDA Product within the United States, including in New Jersey, consistent with Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Defendants regularly do business in New Jersey, and their practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, Defendants' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On information and belief, the Xiromed

ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the patents-in-suit in the event that the Xiromed ANDA Product is approved before the patents-in-suit expire.

30. On information and belief, Defendants derive substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and that are manufactured by Defendants and/or for which Xiromed España, Xiromed, LLC, and/or Insud is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Xiromed España, Xiromed, LLC and/or Insud is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in New Jersey.

31. Venue is proper in this Court as to Xiromed España because Xiromed España is a foreign entity that may be sued in any judicial district, including in the District of New Jersey. *See* 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

32. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Xiromed, LLC, because, on information and belief, Xiromed, LLC is organized under the laws of the State of New Jersey, has a regular and established place of business in New Jersey, and because, on information and belief, Xiromed, LLC has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the patents-in-suit that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing Xiromed's ANDA in New Jersey and/or with the intention of seeking to market the Xiromed ANDA Product nationwide, including within New Jersey.

33. Venue is proper in this Court as to Insud because Insud is a foreign entity that may be sued in any judicial district, including in the District of New Jersey. *See* 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT

34. The '037 patent is entitled "X-Ray Visible Drug Delivery Device" and is attached as Exhibit A.

35. The '037 patent was duly and legally issued on May 13, 2014.

36. The '037 patent is directed generally to X-ray visible implant compositions comprising crystalline etonogestrel (also known as 3-ketodesogestrel) or desogestrel for subdermal administration.

37. The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") currently lists the expiration of the '037 patent as September 28, 2027.

38. The '552 patent is entitled "Applicator for Inserting an Implant" and is attached as Exhibit B.

39. The '552 patent was duly and legally issued on September 12, 2017.

40. The '552 patent is directed generally to an applicator for subdermally inserting an implant containing etonogestrel that prevents the unintended exit of the implant from the applicator or damage to the implant prior to or during insertion in a patient.

41. The Orange Book currently lists the expiration of the '552 patent as July 28, 2030.

THE NEXPLANON® DRUG PRODUCT

42. NEXPLANON® is a groundbreaking innovation in the field of contraception. Organon USA is the holder of NDA No. 021529, under which the FDA approved the commercial marketing of NEXPLANON® (etonogestrel implant, 68 mg/implant) on May 13, 2011, under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a).

43. NEXPLANON® has two primary components: (1) a matchstick-sized, radiopaque implant containing etonogestrel, a synthetic hormone that prevents pregnancy by inhibiting ovulation, and (2) a novel applicator device used to insert the implant subcutaneously at the proper location in the upper arm. Once inserted, a single NEXPLANON® implant systemically delivers an ongoing low dose of etonogestrel into the bloodstream for up to three (3) years, which then prevents ovulation in the ovaries. When used correctly, NEXPLANON® is over ninety-nine (99) percent effective at preventing pregnancy. A true and correct copy of the current prescribing information for NEXPLANON® is attached as Exhibit C.

44. NEXPLANON®, as well as methods of using NEXPLANON®, are covered by one or more claims of the patents-in-suit. The '037 and '552 patents are listed with NDA No. 021529 in the FDA's Orange Book.

DEFENDANTS' ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

45. On information and belief, Xiromed has submitted, or caused the submission of, Xiromed's ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Xiromed ANDA Product, as a purported generic version of NEXPLANON®, prior to the expiration of the patents-in-suit.

46. On information and belief, the FDA has not yet approved Xiromed's ANDA.

47. In the Xiromed Notice Letter, Xiromed notified Plaintiffs of the submission of Xiromed's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Xiromed ANDA Product prior to the expiration of the patents-in-suit.

48. On information and belief, the Reference Listed Drug for Xiromed's ANDA is NEXPLANON®. NEXPLANON® is indicated for use by women to prevent pregnancy.

49. On information and belief, the Xiromed ANDA Product contains 68 mg etonogestrel per implant.

50. On information and belief, Xiromed, through its own actions and through the actions of its agents, affiliates, and subsidiaries, prepared and submitted Xiromed's ANDA, and intends to further prosecute Xiromed's ANDA. On information and belief, if the FDA approves Xiromed's ANDA, Xiromed will manufacture, offer for sale, or sell the Xiromed ANDA Product within the United States, or will import the Xiromed ANDA Product into the United States. On information and belief, if the FDA approves Xiromed's ANDA, Xiromed will directly manufacture, use, offer for sale, sell, or import the Xiromed ANDA and/or actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Xiromed ANDA Product in or into the United States.

51. Plaintiffs bring this action within forty-five (45) days of receipt of the Xiromed Notice Letter. Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I – INFRINGEMENT OF THE '037 PATENT

52. Plaintiffs incorporate each of the preceding paragraphs 1-51 as if fully set forth herein.

53. The Xiromed ANDA Product, and the use of the Xiromed ANDA Product, is covered by one or more claims of the '037 patent including, but not limited to, claim 1 of the '037 patent.

54. In the Xiromed Notice Letter, Xiromed did not contest infringement of claims 1-24 of the '037 patent. If Xiromed had a factual or legal basis to contest infringement of those claims of the '037 patent, then it was required by applicable regulations to state such a basis in the Xiromed Notice Letter. *See* 21 C.F.R. § 314.52 (requiring a Paragraph IV notice letter to include

a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug as to which the applicant has submitted a Paragraph IV Certification). Thus, Xiromed has conceded infringement of the '037 patent.

55. Xiromed's submission of Xiromed's ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Xiromed ANDA Product in or into the United States before the expiration of the '037 patent is an act of infringement of the '037 patent under 35 U.S.C. § 271(e)(2)(A).

56. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will infringe one or more claims of the '037 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States.

57. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will induce infringement of one or more claims of the '037 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or distribute the Xiromed ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Xiromed will knowingly and intentionally accompany the Xiromed ANDA Product with a product labeling or product insert that will include instructions for using or administering the Xiromed ANDA Product, which are substantially similar to the instructions in the prescribing information

for NEXPLANON®, attached as Exhibit C, and which, if followed, will infringe the '037 patent. Accordingly, Xiromed will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and/or other end users of the Xiromed ANDA Product to directly infringe the '037 patent. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will intentionally encourage acts of direct infringement with knowledge of the '037 patent and knowledge that its acts are encouraging infringement.

58. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will contributorily infringe one or more claims of the '037 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States. On information and belief, Xiromed has had and continues to have knowledge that the Xiromed ANDA Product is especially adapted for a use that infringes one or more claims of the '037 patent, including at least claim 1, and that there is no substantial non-infringing use for the Xiromed ANDA Product.

COUNT II – INFRINGEMENT OF THE '552 PATENT

59. Plaintiffs incorporate each of the preceding paragraphs 1-58 as if fully set forth herein.

60. The Xiromed ANDA Product, and the use of the Xiromed ANDA Product, is covered by one or more claims of the '552 patent including, but not limited to, claim 14 of the '552 patent.

61. In the Xiromed Notice Letter, Xiromed did not contest the validity of claims 1-25 of the '552 patent. If Xiromed had a factual or legal basis to contest validity of those claims of the '552 patent, then it was required by applicable regulations to state such a basis in the Xiromed Notice Letter. *See* 21 C.F.R. § 314.52 (requiring a Paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that

is listed in the Orange Book in conjunction with the reference listed drug as to which the applicant has submitted a Paragraph IV Certification). Thus, Xiromed has conceded validity of the '552 patent.

62. Xiromed's submission of Xiromed's ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Xiromed ANDA Product in or into the United States before the expiration of the '552 patent is an act of infringement of the '552 patent under 35 U.S.C. § 271(e)(2)(A).

63. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will infringe one or more claims of the '552 patent under 35 U.S.C. § 271(a), including at least claim 14, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States.

64. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will induce infringement of one or more claims of the '552 patent under 35 U.S.C. § 271(b), including at least claim 14, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or distribute the Xiromed ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Xiromed will knowingly and intentionally accompany the Xiromed ANDA Product with a product labeling or product insert that will include instructions for using or administering the Xiromed ANDA Product, which are substantially similar to the instructions in the prescribing information for NEXPLANON®, attached as Exhibit C, and which, if followed, will infringe the '552 patent.

Accordingly, Xiromed will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and/or other end users of the Xiromed ANDA Product to directly infringe the '552 patent. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will intentionally encourage acts of direct infringement with knowledge of the '552 patent and knowledge that its acts are encouraging infringement.

65. On information and belief, upon FDA approval of Xiromed's ANDA, Xiromed will contributorily infringe one or more claims of the '552 patent under 35 U.S.C. § 271(c), including at least claim 14, by making, using, offering to sell, selling, and/or importing the Xiromed ANDA Product in or into the United States. On information and belief, Xiromed has had and continues to have knowledge that the Xiromed ANDA Product is especially adapted for a use that infringes one or more claims of the '552 patent, including at least claim 14, and that there is no substantial non-infringing use for the Xiromed ANDA Product.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

a) A judgment that the '037 patent has been infringed under 35 U.S.C. § 271(e)(2) by Xiromed's submission to the FDA of Xiromed's ANDA;

b) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of the Xiromed ANDA Product, or any other drug product that infringes or the use of which infringes the '037 patent, be no earlier than the expiration date of the '037 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

c) A judgment that the '552 patent has been infringed under 35 U.S.C. § 271(e)(2) by Xiromed's submission to the FDA of Xiromed's ANDA;

d) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of the Xiromed ANDA Product, or any other drug product that infringes or the use of which infringes the ’552 patent, be no earlier than the expiration date of the ’552 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

e) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Federal Rule of Civil Procedure 65, enjoining Xiromed, and all persons acting in concert with Xiromed, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Xiromed ANDA Product, or any other drug product covered by or whose use is covered by the patents-in-suit prior to the expiration of the patents-in-suit inclusive of any extension(s) and additional period(s) of exclusivity;

f) A judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Xiromed ANDA Product, or any other drug product that is covered by or whose use is covered by the patents-in-suit, prior to the expiration of the patents-in-suit, inclusive of any extension(s) and additional period(s) of exclusivity, will infringe, induce the infringement, and contribute to the infringement by others of the patents-in-suit;

g) A judgment declaring that Xiromed’s commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Xiromed ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the patents-in-suit by Xiromed under one or more of 35 U.S.C. §§ 271(a), (b), and (c);

h) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Xiromed engages in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Xiromed ANDA Product, or any product that infringes the patents-in-suit, or induces or contributes to such conduct, prior to the expiration of the patents-in-suit, inclusive of any extension(s) and additional period(s) of exclusivity;

i) A judgment that Xiromed willfully and deliberately infringed the patents-in-suit;

j) A declaration that this is an exceptional case, and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

k) Costs and expenses in this action; and

l) Such further and other relief as this Court may deem just and proper.

Dated: April 2, 2025
Newark, New Jersey

s/ William P. Deni, Jr.
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